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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/506,727 | 10/18/2004 | Marcel Braun | 112701-435 | 5245 |

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| EXAMINER | |
|---|---|
| HAMIDINIA, SHAWN A | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1653 | |

DATE MAILED: 05/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/506,727 | BRAUN ET AL. | |
| | Examiner | Art Unit | |
| | Shawn Hamidinia | 1653 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *18 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction is unnecessary.

### *Priority*

2. The current application filed on October 18, 2004 is a 371 of PCT/EP03/00411 filed on January 16, 2003, which claims benefit of foreign application EP 02004880.7 filed on March 4, 2002.

### *Information Disclosure Statement*

3. No information disclosure statements have been received.

### *Claim Rejections - 35 USC § 112, Second Paragraph*

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1, 2, 13 and 20 are rejected under 35 U.S.C. 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 2-9, 12 and 15-18 are also rejected as being dependent from rejected claim 1 and failing to cure the defect.

6. In claim 1 the applicant uses the term cGMP. This term is improper, because the claim reads on cyclic-guanosine-monophosphate. Revising the claim to spell out the abbreviation, "caseino-glycomacropeptide (cGMP)", will overcome this objection.

7. Claims 2, 13 and 20 contains the trademark/trade names Serdolith III, Lewatit EP-63, Lewatit OC 1064, Lewatit OC 1066, Lewatit VC-OC, and Amberlite XAD. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademarks/trade names are used to identify polymeric adsorbent resins and, accordingly, the identification/description is indefinite.

***Claim Rejections - 35 USC § 101 & 35 USC § 112***

8. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

9. Claims 11 and 19 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible asserted utility or a well-established utility. Claims 20-26 are also rejected as being dependent from rejected claim 19 and failing to cure the defect.

The applicants' elected invention is for a method of treating or preventing a disease chosen from caries, plaque formation, dental diseases, diseases of the mouth cavity and diseases of the gums by administering to an individual a therapeutically effective amount of cGMP comprising a hydrophobic resin and an agent that blocks functional groups in cGMP.

Claims 11 and 19 are considered to meet the specific and substantial utility guidelines for the prevention and or treatment of caries, plaque formation, dental diseases, diseases of the mouth cavity and diseases of the gums. However, claims 11 and 19 are not a credible or well-established utility for the prevention of caries, plaque formation, dental diseases, diseases of the mouth cavity and diseases of the gums.

With regard to specific utility, the specification discloses that the cGMP composition would be useful for the prevention and/or treatment of caries, plaque formation, dental diseases, diseases of the mouth or gums. Claims 11 and 19 meet a specific utility because a specific disease and related disorders are disclosed to be treated, rather than an unspecified disease. Thus, there is sufficient disclosure of what the condition is to be treated.

With regard to substantial utility, claims 11 and 19 are supported by a substantial utility because the prevention and/or treatment of caries, plaque formation, dental

diseases, diseases of the mouth cavity and diseases of the gums do constitute a "real world use". Page 11 of the specification describes that due to its microbizidal activity, cGMP is utilized in formulations for treating bacteria in the buccal cavity which are responsible for the formation of dental plaque and caries.

The "prevention" of caries, plaque formation, dental diseases, diseases of the mouth cavity and diseases of the gums is not a credible utility. A credible utility is assessed from the standpoint of whether a person of ordinary skill in the art would accept that the recited or disclosed invention is currently available for such use. The specification as filed does not disclose or provide any evidence that points to prevention of the above diseases and furthermore there is no art of record that discloses or suggests preventing these diseases with the claimed plaque associated molecules. Zhang et al. (US Pat # 5,853,704) describes that casein glycomacropeptides (cGMP) have been identified in the art to be effective antibacterial agents against micro-organisms responsible for dental plaque and caries when applied to the tooth and periodontium, (see lines 26-33, column 1). However, Zhang et al., nor any other art of record, do not describe that cGMP prevents dental plaque and carries. Thus, "**further studies are warranted**", particularly: (1) a comparison between the relative effectiveness of cGMP upon blocking the functional groups in cGMP and (2) the effectiveness of cGMP after prolonged storage. In order to prove that the instant invention prevents caries, plaque formation, dental diseases, etc., long-term studies must be undertaken which conclusively demonstrate that caries, plaque formation, and dental diseases do not develop in any individual tested. Neither the specification as

filed nor any other art of record discloses such a study. Because the claimed invention is not supported by a credible and well-established utility for the reasons above, claims 11 and 19 are rejected under 35 U.S.C. 101.

Claims 11 and 19 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

***Claim Rejections - 35 USC § 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 1-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhang et al. (US Pat # 5,853,704) and Higashi et al. (US Pat # 4,530,906) in view of Agmon et al.

Zhang et al. teach an anticaries dentrifice composition and method of use therefore, having a first component containing a fluoride ion source, and a second component containing a casein glycomacropeptide, (see lines 6-14, column 1; claims 1, 11). Zhang et al. further teach that casein glycomacropeptides (cGMP) are known in the art to be effective antibacterial agents against micro-organisms responsible for

dental plaque and caries when applied to the tooth and periodontium, (see lines 26-31, column 1). Zhang et al. also teach that casein glycomacropeptide compounds are slightly acidic in nature and it is taught that the ideal pH shall be in a neutral range, preferably between pH 6.7 and 7.2, (see lines 43-50, column 4). Zhang et al. teach that other ingredients may be incorporated with the components of the invention which include from about 0.05 to about 5% of an antibacterial enhancing agent (AEA) such as maleic anhydride, (see lines 39-56, column 5). Zhang et al. further teach that the components of the invention can be introduced into the form of toothpaste, (see lines 45-51, column 6). Zhang et al. do not teach the hydrophobic resin (i) which is a component of the instant claimed invention.

Agmon et al. teach a process for treating food products and by-products to remove off-flavors, off-colors and off-smells associated with food products and by-products such as dairy products and by-products, (see lines 19-29, page 2). Agmon et al. discuss that adsorbent resins (see lines 32-47, page 3) are used in the process of the invention to remove off-tastes and off-smells from dairy products and by-products and cite examples of polymeric adsorbent resins which include Amberlite XAD-4, Amberlite XAD 16 and Amberlite XAD-7, (see lines 28-32, page 4). Agmon et al. further clarify that the food products and by-products treated in their invention are selected from dairy products, milk products or by-products thereof, (see lines 45-50, page 2). Page 11 of the instant specification describes cGMP as a glycosylated compound formed during the enzymatic cleavage of kappa-casein from the milk of mammals by the action of

rennet or pepsin. Therefore, cGMP is clearly a by-product of milk and is encompassed by the invention described by Agmon et al.

Higashi et al. teach that it is well known in the art that when a protein is treated with maleic anhydride or succinic anhydride, the amino groups in the protein are mainly acylated, (see lines 34-47, column 3). Higashi et al. further describe that when succinic anhydride is used, the succinic group bound to the amino group is much more stable under acidic conditions than the maleyl group bound to the amino group, (see lines 15-20, column 4). Furthermore, Higashi et al. teach that *Mucor pusillus* microbial rennet acylated with succinic anhydride can overcome the various troubles encountered in the production of cheese by conventional microbial rennet preparations, such as the reduced yield of the curd, bitter taste and it has excellent stability and safety during the storage or its use in the cheese making process, (see lines 31-65, column 5; lines 9-17, column 9). Higashi et al. teach that the pH of the reaction mixture during the acylation is about 4 to about 10, preferably about 7 to about 9, (see lines 9-15, column 5).

A person of ordinary skill in the art at the time the invention was made would have been motivated to substitute an cGMP composition with a by-product of milk because both have the same form and purpose.

Hence, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to use a cGMP composition which contains an agent which chemically blocks functional groups in cGMP following the teachings of Zhang et al. and Higashi et al. in order to gain the advantages of removing off-flavors and off-

smells from milk and its by-products by adding hydrophobic resins such as Amberlite XAD as taught by Agmon et al.

***Conclusion***

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shawn Hamidinia whose telephone number is (571) 272-4534. The examiner can normally be reached on Mon-Fri from 9:00 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SAH

ROBERT A. WAX
PRIMARY EXAMINER